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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,193	03/28/2001	Charleata A. Carter	8263.03	2906

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,193

Applicant(s)

CARTER

Examiner

Karen A Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-29 and 31-43 is/are pending in the application.
4a) Of the above claim(s) 31-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 21-29 and 40-43 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 14-20 and 30 have been canceled. Claims 40-43 have been added. Claims 21-29, 31-43 are pending. Claims 31-39 remain withdrawn from consideration. Claims 21-29 and 40-43 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action

Claims 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is vague and indefinite in the recitation of a karyotype including “?”. because the “?” indicates questionable identification of chromosome or chromosome structure. Thus the metes and bounds of the cell lines encompassed by the recited karyotype is unknown.

Amendment of the claim to recite a Deposit Accession number will overcome this rejection,

Claim 43 is drawn to a human endometrial adenocarcinoma cell line designated CAC-1 having all the identifying characteristics of CAC-1 cells. The metes and bound of CAC-1 cells cannot be determined because the specification does not provide a limiting definition for the identifying characteristics of CAC-1 cells. The specification discusses cell lines which differ from the CAC-1 cell line on pages 15-18. However, describing what limiting characteristics are not present in the claimed product does not provide limitations for what the product actually is. because it characterizes the claimed cell line by excluding what the inventor did not invent rather than distinctly and particularly pointing out what she did invent. In re Schechter, 205 F.2d 185, 98 USPQ 144 (CCPA 1953). Page 26, lines 1-8 state that “CAC-1 cells originate from glandular epithelial cells forming a primary tumor of the endometrium of the uterus” and that in general, “these cells are poorly differentiated and highly invasive”. the statement that the poor differentiation and highly invasive characteristic is a characteristic “in general” does not provide a limiting characteristics of CAC-1 cells. The specification further states that “another distinguishing characteristic may be that typical CAC-1 cells are hyperdiploid”. Again this recitation that “typical CAC-1 cells may be hyperdiploid” does not provide a limiting structural

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characteristic which would require every CAC-1 cell to possess such characteristics.

Amendment of the claim to recite a deposit accession number will overcome this rejection, however, the amendment of the instant claim and claim 25 would result in both of claims 25 and 43 being duplicate claims.

The rejection of claim 25 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for lacking a deposit of biological material is maintained for reasons of record. Applicants intention of making the required deposit after indication of allowability is noted, however, the examiner will not rejoin the method claims to the product claims until the product claims are deemed to be allowable.

Claims 26-29, 41, 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 26 is drawn to a cell line originating from a primary tumor specimen of a poorly differentiated human endometrial adenocarcinoma, wherein a plurality of cells differentiated in response to an anti-cancer compound. Claim 27 embodies the cell line of claim 26 wherein said anti-cancer compound comprises protein kinase inhibitor. Claim 28 embodies the cell line of claim 27 wherein said protein kinase inhibitor comprises a retinoic acid treatment.. Claim 41 embodies the cellular composition of claim 21 wherein a plurality of cells are triploid at chromosomes 3, 7 and 17, but only haploid at chromosome 14. Claim 42 embodies the cellular composition of claim 21 wherein a plurality of cells are triploid at chromosomes 3, 7 and 17, but only haploid at chromosome 14 and wherein said cellular compositions contains a plurality of cells having 48 chromosomes .

Claims 26, 27 and 28 are drawn to a genus of cell lines originating from a poorly differentiated tumor, wherein said cells have the ability to differentiate in response to an anti-cancer compound, specifically, a retinoic acid. The art recognizes that poorly differentiated endometrial cellular retinoid binding proteins are overexpressed in poorly differentiated endometrial tumors (Siddiqui et al (International Journal of Cancer, 1995, vol.64, pp. 253-263,

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especially page 257, under the heading of “Expression of mRNA for the cellular retinoid binding proteins in endometrial adenocarcinoma”). The art teaches that elevated levels of intracellular retinoic acid facilitate differentiation to a glandular phenotype (Siddiqui et al, page 261, second column, lines 6-12 of the first full paragraph) and that elevated levels of retinoic acid binding proteins compete for the intracellular retinoic acid and thus contribute to maintaining the poorly differentiated grade 3 tumors (lines in the more aggressive and poorly differentiated grade 3 tumors. (page 261, second column, lines 12-18). Thus, one of skill in the art would reasonable conclude that the presence of the elevated levels of retinoic acid binding proteins in Stage 3 endometrial adenocarcinoma prevents accumulation of intracellular retinoic acid necessary for differentiation. The instant claims relied upon the identity of a cell line originating from a poorly differentiated endometrial adenocarcinoma. Said cell line having the ability to differentiate in response to retinoic acid treatment which would be unexpected in light of the teaching of the art regarding tumor samples overexpressing the retinoic acid binding proteins. Thus, it would be necessary to have such a cell line in order to carry out the limitation of the claims. The specification teaches the isolation of the CAC-1 cell line but does not teach how to isolate CAC-1 cell lines from any other patients, nor does it teach how to isolate endometrial adenocarcinoma cells of STAGE 3 which would have the characteristics of differentiating in response to retinoic acid treatment. Given the teachings of the specification, one of skill in the art could not be assured of being able to isolate a cell line having of poorly differentiated adenocarcinoma of the uterine endometrium which would have the claimed characteristic of differentiating in response to retinoic acid treatment. Thus, one of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to obtain the claimed cell lines.

Claims 21-24 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Satyaswaroop et al (In: In Vitro Models for Cancer Research, Vol. III, 1986, CRC Press, M. Webber, Ed., page 197, Figure 4) as evidenced by Trent (In: In Vitro Models for Cancer Research, Vol. III, 1986, CRC Press, M. Webber, Ed., page 183).

Claim 21 is drawn to a hyperdiploid cellular composition comprising cells isolated from a poorly differentiated primary tumor of glandular epithelial cells of the endometrium of the

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uterus. Claim 22 embodies the composition of claim 21 wherein a plurality of cells have an average of 48 chromosomes. Claim 23 embodies the composition of claim 22 wherein a plurality of cells are triploid at chromosome 3. Claim 24 embodies the composition of claim 22 wherein a plurality of cells are triploid at chromosome 17. Claim 40 embodies cellular composition of claim 22 wherein a plurality of cells are triploid at chromosome 7.

Satyaswaroop et al disclose a cellular composition comprising endometrium with poorly differentiated adenocarcinoma, fulfilling the specific embodiment of cells isolated from a poorly differentiated primary tumor of glandular epithelial cells of the endometrium of the uterus (Figure 4, page 197). Trent discloses that carcinomatous endometrium hyperdiploidy with minimal change, with trisomy of a single chromosome to be quite common (page 183, lines 7-10). Thus it appears that the adenocarcinoma composition disclosed by Satyaswaroop et al would contain some cells having an average of c48 chromosomes by virtue of a trisomy. Although neither of Satyaswaroop et al nor Trent specifically teach that a poorly differentiated adenocarcinoma of the endometrium of the uterus would contain cells having a trisomy at chromosomes 3, 7 or 17, the claimed cellular compositions appears to be the same as the prior art cellular composition, absent a showing of unobvious differences. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Applicant is advised to claim a single cell line qualified by a Deposit Accession Number, and evoke rejoinder to the method claims in order to further the prosecution.

All other rejections and objections as set forth in the previous Office action are withdrawn in light of applicants amendments.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A Canella, Ph.D.

7/26/2004


KARENA. CANELLA PH.D
PRIMARY EXAMINER